REMARKS

Initially, Applicants would like to thank the Examiner for granting the telephone interview on April 29, 2004, regarding this application. A letter outlining issues to be discussed was sent to the Examiner on April 28, 2004 (copy attached hereto as "Exhibit A"). This letter and the remarks below serve as a summary of the interview.

In the Final Office Action dated September 10, 2003, the Examiner rejected claims 1-3, 5-6, and 10-14 for lack of written description. Independent claim 1 covered a Lac shuttle vector containing, among others, a nucleic acid sequence encoding a protein involved in replication of a lactic acid bacterial plasmid. Independent claim 13 covered a vaccine composition having the just-described Lac shuttle vector. It was the Examiner's position that the specification provides no limitation on how the protein might be involved in the replication. In the response filed February 10, 2004, Applicants pointed out that the specification did provide such limitation. That is, the protein is involved in the replication through binding to DNA. Indeed, the specification discloses a Lac shuttle vector having a nucleic acid sequence encoding a Rep A protein, which is a DNA-binding protein. However, in the Advisory Action dated March 16, 2004, the Examiner asserted that the claims 1 and 13 did not recite "DNA-binding protein." During the telephone interview, Applicants' counsel proposed reciting "DNA-binding protein" in claims 1 and 13. The Examiner expressed his concern that the term was not clear enough, and suggested reciting "Rep A protein" and "consisting essentially of" in the claims to limit the term at issue to Rep A protein and its functional equivalents.

In the Final Office Action and Advisory Action, the Examiner also rejected claim 13 for lack of enablement, alleging that it "encompass[ed] a DNA vaccine composition comprising any antigenic genes." During the telephone interview, Applicants discussed with the Examiner possible amendments that would overcome the rejection. The Examiner suggested replacing "vaccine composition" recited in the claim with "immunogenic composition."

For the purpose of moving this case toward allowance, Applicants have filed herewith a Request for Continued Examination and amended claims 1 and 13, as suggested by the Examiner. Applicants have also added new claims 15 and 16. Support for "Rep A protein" can

be found at page 7, lines 24-27.[1] Support for "immunogenic composition" can be found at page 10, lines 10-13 and lines 27-29.[2] No new matter is introduced.

Upon entry of the amendments, claims 1-16 are pending and under examination. In view of the above amendments and remarks, as well as the remarks provided in the last response, Applicants submit that the grounds for the rejections asserted by the Examiner have been overcome, and that claims, as pending, define subject matter that sufficiently described and fully enabled. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

This response is being filed concurrently with a Request for Continued Examination and the required $385.00 fee. Please apply any other charges to Deposit Account No. 06-1050, referencing Attorney Docket No. 12875-002001.

Respectfully submitted,

Date: 5-11-04

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[1]This passage discloses that a Lac shuttle vector of this invention has a sequence encoding a Rep A protein. The function of a Rep A protein in replication is well known in the art. See, e.g., Bouia A., et al., 1989, Plasmid, 22: 185-192 and Bringer F., et al., 1989, Plasmid 22: 193-202. A specific Rep A protein was used by Applicants as an example in the specification. Its variants retaining the same function are known in the art.

[2] According to the first of these two passages, a Lac shuttle vector of this invention has a sequence encoding a protein that is "antigenic," i.e., immunogenic. The second passage discloses that a composition of this invention "can stimulate ... the immune response... " In other words, the composition is immunogenic.

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VIA FACSIMILE

April 28, 2004

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Re: Novel Vector
Application No.: 09/778,516
Our Ref.: 12875-002001

FR

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Dear Examiner Sullivan:

Thank you for granting a telephone interview, scheduled for 10:00 am, April 29, 2004 to resolve issues raised in the final office action and the advisory action. This letter is limited to independent claims 1 and 13 to facilitate discussion.

You rejected claim 1 for lack of written description. This claim covers a Lac shuttle vector containing, among others, a nucleic acid sequence encoding a protein involved in replication of a lactic acid bacterial plasmid. It is your position that the specification provides no limitation on how the protein might be involved in the replication. In the response filed February 10, 2004, we pointed out that the specification provided such limitation. That is, the protein is involved in the replication through binding to DNA. Indeed, the specification discloses a Lac shuttle vector having a nucleic acid sequence encoding Rep A protein, which is a DNA-binding protein. However, you countered that the claim does not recite "DNA-binding protein." For the sole purpose of moving this case toward allowance, we propose amending claim 1 as follows:

1. A Lac shuttle vector, comprising:

(a) a region which regulates a plasmid copy number, wherein said region comprises an E. coli replication origin sequence;

(b) a eukaryotic gene expression cassette, which comprises a eukaryotic gene transcriptional promoter sequence, a multiple cloning site and a transcriptional terminator sequence, wherein a desired gene is inserted into said multiple cloning site;

(c) a lactic acid bacterial plasmid sequence, which comprises a plus origin of replication, and a nucleic acid sequence encoding a DNA-binding protein which is involved in replication of the lactic acid bacterial plasmid; and

(d) a marker gene that is not an antibiotic resistance gene and is operably linked to a promoter sequence.

This amendment is supported by the specification (see, e.g., page 7, lines 24-25) and does not necessitate a new search.

You also rejected claim 13, drawn to a DNA vaccine containing the above-discussed Lac shuttle vector, for lack of enablement. It is your position that this claim "encompass[es] a DNA vaccine composition comprising any antigenic genes," the majority of which would be inoperative. We pointed out that, since it was routine for one skilled in the art to test the operativeness of a certain vaccine, claim 13 met the enablement requirement. Apparently, you were not convinced and emphasized again in the advisory action that the claim is unlimited as to the antigenic genes. We are willing to narrow the scope of this claim and would like to discuss our proposal with you during the interview.

We look forward to speaking to you.

Very truly yours,

Y. Rocky Tsao

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